

## **REMARKS/ARGUMENTS**

### **I. Status of the Claims**

Claims 1-5 are presently pending. Claims 1, 2, and 5 are amended and new claim 6 is added. No new matter is introduced. Support for the amendments may be found, for example, with reference to Applicant's specification at p. 8, lines 7 - 20, p. 26, lines 15 - 17, Examples 1-7, and Table 2.

### **II. Status of the Specification**

The title has been amended to better describe the nature of the invention.

### **III. Claims Rejections under 35 U.S.C. § 112**

Claims 1 - 5 are rejected for lack of enablement. According to the Examiner, claims 1-5 are rejected because the specification fails to teach a method for making a Na<sub>2</sub>O coated metal hydroxide particle. Specifically, the Examiner contends that the Applicant and the prior art do not explain how to make the coated particle and a person would be relegated to trial and error methods of producing the particle. The Applicant respectfully traverses this rejection.

As set forth below, one of ordinary skill in the art could practice the invention without undue experimentation.

To be enabling, the specification must teach one of ordinary skill in the art to make and use the full scope of the claimed invention without "undue experimentation." *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). As long as "undue experimentation" is not involved, a specification complies with the enablement requirement, even if a reasonable amount of routine experimentation is required to practice the invention. *Enzo Biochem Inc. v. Calgene*, 188 F.3d 1362, 1371, 52 U.S.P.Q.2d 1129, 1135 (Fed. Cir. 1999). Even "a considerable amount of experimentation is permissible, if it is merely routine." *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

It is the Examiner's burden to provide a reasonable explanation of why the specification does not enable the scope of the pending claims. *In re Wright*, 999 F.2d 1557, 1561-1562, 27 U.S.P.Q.2d 510, 1513 (Fed. Cir. 1993).

The following analysis of the claimed invention using the factors regarding enablement set forth in *In re Wands* illustrates that it would not require undue experimentation to practice the claimed invention.

The nature of the invention. The nature of the invention is an injection molded object formed from a resin composition that includes a lactic acid based resin and a Na<sub>2</sub>O-surface treated metal hydroxide blended with the lactic acid based resin in a certain ratio.

The state of the prior art. The state of the prior art is advanced. Injection molded plastic has been studied for many years and injection molding does not represent a new or unpredictable area of science. Furthermore, flame retardants that contain neither halogen nor phosphorus have been under development. Specification, p. 3, lines 1-5. Furthermore, well-known methods of surface treating methods for a metal hydroxide are included within the specification. Specification, p. 8, lines 7-20.

The relative skill in the art. The level of skill in the art is high. Thus, it would not be expected that undue experimentation would be required for a person of ordinary skill to make and use the invention as presently claimed because such a person would know a method to make a Na<sub>2</sub>O surface treatment, based on the specification at p.7, lines 5-19, and the different methods of surface treatment that can be used apply this treatment to the invention.

The predictability or unpredictability of the art. The nature of the invention is an injection molded object formed from a resin composition that includes a lactic acid based resin and a Na<sub>2</sub>O-surface treated metal hydroxide blended with the lactic acid based resin in a certain ratio. Biodegradable resins that include lactic acid based resin in combination with other polyesters have excellent transparency, rigidity, heat resistance and are a substitute material for less biodegradable resins. Specification, p. 2, lines 1-9. Based on the prior art and current experimentation, this specific invention that includes surface treatment of metal oxides is well-known within the art and would not be unpredictable.

The amount of direction or guidance presented. The Examiner states that given that the specification fails to teach a method for making a Na<sub>2</sub>O coated metal hydroxide particle and that the prior art does not teach a method for coating, “it is exceedingly difficult to practice the invention” and “one would be relegated to ‘trial and error.’”

Routine research, even if extended, is permissible as long as the specification provides sufficient direction or guidance to the skilled artisan. MPEP § 2164.06. Here, the specification discloses the method for obtaining the amount of w-Na<sub>2</sub>O used in the treatment. Specification, p. 7, lines 5-19. Further, the specification lists various methods of surface treatment for the metal hydroxide. The specification states that the metal hydroxide used in the present invention is preferably surface-treated by one or more of these surface-treating methods. These parameters provide adequate guidance for those skilled in the art to conduct reasonable, not undue, experimentation, and to readily utilize compounds in the claimed methods. Therefore, the claims are adequately enabled by the specification.

The quantity of experimentation needed. Applicant disclosed the basis of the invention, information to make the surface treatment, and methods on how to apply it. Applicant submits that the disclosure of this invention are more than general ideas that may or may not be workable. In contrast, the Examiner has failed to raise and substantiate a reasonable doubt of the objective truth of the statements contained in the disclosure. Therefore, the Examiner has not met the burden required to raise a proper enablement rejection. MPEP § 2164.04.

In view of the foregoing, claims 1-5 would not require undue experimentation and the Examiner has not yet established a prima facie case of non-enablement. The Applicant respectfully requests that this rejection be withdrawn.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph for failing to define the metes and bounds of the claim in regards to the term “aromatic aliphatic.” The Examiner states that the term “aromatic aliphatic” is indefinite because the specification does not clearly define the term. Claim 2 has been amended and does not include the term “aromatic-aliphatic” and so the Examiner’s rejection for lack of indefiniteness is moot. Applicant respectfully requests that this rejection be withdrawn.

New claim 6 includes the term. Claims 3 and 13-16 are rejected under 35 U.S.C. § 112, second paragraph for failing to define the metes and bounds of the claim in regards to the term “aromatic aliphatic.” The Examiner states that the term “aromatic aliphatic” is indefinite because the specification does not clearly define the term. Applicant respectfully traverses the rejection on the grounds that the term is used according to its ordinary meaning as understood by one of ordinary skill in the field of synthetic biodegradable polymers. Krystyna Twarowska-Schmidt and Maria Ratajska use the term in their paper, stating that “aromatic-aliphatic polyester containing structural units of typical terephthalic polyesters, aliphatic polyesters like poly(ethylene adipate) and other polyesters based on dicarboxylic acids are a member of the synthetic biodegradable polymers”. Krystyna Twarowska-Schmidt and Maria Ratajska, *Biodegradability of Non-Wovens Made of Aliphatic-Aromatic Polyester*, Institute of Chemical Fibres, January/March 2005, Vol 13. No. 1 (49), [http://www.fibtex.lodz.pl/49\\_21\\_71.pdf](http://www.fibtex.lodz.pl/49_21_71.pdf). Ilona Kleeberg, et. al. also use the term in their research to describe a copolymer using terephthalic acid, adipic acid and 1,4-butanediol as an aromatic-aliphatic polyester. *Biodegradation of Aliphatic-Aromatic Copolyesters by Thermoospora fusca and Other Thermophilic Compost Isolates*, Appl Environ Microbiol. 1998 May 64(5): 1731-1735, <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=106223>). This combination of polymers is recommended in the current specification at p. 19, paragraph 98. Thus, it is well understood in the art that “aromatic-aliphatic polyester” include biodegradable aromatic aliphatic polyesters consisting of one or more aromatic and aliphatic polyester. Accordingly, the term is used to its ordinarily accepted meaning. Thus the term is not “an oxymoron.” In short, one of ordinary skill in the art would readily understand the metes and bounds of the term. The present rejection should be withdrawn. Even though the Applicant respectfully disagrees with the Examiner’s arguments, Applicant has amended all claims referencing “aromatic aliphatic polyester” to “aromatic-aliphatic polyester” as that is the most common spelling for the term within the field.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, for failing to distinctly point out the metes and bounds of the claim. The Examiner contends that the limitation “has a degradation rate of 10% or less” fails to distinguish between a rate (a

measure of change as a function of time) and a percentage. The Examiner states that a degradation rate of 10% per year is different than a degradation rate of 10% per day and therefore the metes and bounds are not distinctly pointed out. Claim 5 has been amended to change "rate" to the correct term "ratio" as supported at p. 26, lines 15 - 17. Therefore, Applicant contends that the Examiner's argument is moot with this amendment, and respectfully requests withdrawal of the rejection.

**IV. Claims Rejections under 35 U.S.C. § 102**

Claims 1 and 3-4 are rejected under 35 U.S.C. § 102(b) as being anticipated by JP 2002-105298 A ("Shimatzu"). The Examiner alleges that Shimatzu discloses a lactic acid resin and a metal hydroxide present in 1-30%. The Examiner further notes that Applicant's invention claims "less than 0.1% by mass of Na<sub>2</sub>O on the surface of the metal hydroxide", which can include 0%.

Applicant has amended claim 1 to make it clear that the metal hydroxide's surface must be treated with some amount of Na<sub>2</sub>O so that the treatment is greater than 0%. With the amendment, Shimatzu does not cover all aspects of the invention, as it does not disclose a Na<sub>2</sub>O surface-treated metal hydroxide. Applicant submits that with claim 1 amended, the Examiner's argument is moot and requests withdrawal of the rejection of claim 1. For at least these reasons, Applicant respectfully submits that dependent claims 3 and 4 are also not anticipated by Shimatzu and stand in condition for allowance. Applicant therefore respectfully requests that the rejection of the claims under 35 U.S.C. §102 be withdrawn.

**V. Claims Rejections under 35 U.S.C. § 103**

Claim 2 is rejected under 35 U.S.C. § 103(a) as being obvious in view of Shimatzu in view of the Examiner's statement of ordinary skill in the art. Specifically, the Examiner states that Shimatzu discloses that blending a non polylactide aliphatic polyester into a polylactide formulation is known to create a product "excellent in shock

resistance.” The Examiner contends that aliphatic polyester is added to the invention in order to optimize a known effect.

With the amendment of claim 1 to require a minimum amount of  $\text{Na}_2\text{O}$  present on the surface of the metal hydroxide, Applicant submits that the Examiner's argument with respect to claim 2 is moot and respectfully requests withdrawal of the rejection of claims.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: July 23, 2008

Respectfully submitted,

By 

Louis J. DeJundice

Registration No.: 47,522  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 753-6237 (Fax)